Simple Simon PT og MixxoCap/2011/84*

Background
Simple Simon PT was evaluated by SKUP in 2006 under standardised and optimal conditions in a hospital laboratory by experienced laboratory personnel, SKUP/2007/57*. Medic24 and Zafena AB applied to SKUP in October 2010 for an evaluation of MixxoCap; the new Zafena device for collection and handling of capillary samples for Simple Simon PT. SKUP agreed to evaluate the user-friendliness of MixxoCap and the precision of capillary PT (INR) results using Simple Simon PT and MixxoCap. The evaluation was carried out at two primary health care centres where the staff was experienced users of Simple Simon PT.

The aim of the evaluation
- Determination of the repeatability precision when using capillary patient samples collected with MixxoCap
- A comparison of the repeatability achieved with MixxoCap and the repeatability achieved with the primary health care centres' routine methods for measurement of PT (INR)
    - Routine method at Arna Legekontor: venous citrate whole-blood samples analysed on Simple Simon PT
    - Routine method at Legekontoret Kleppestø Senter: capillary samples analysed at Simple Simon PT using the ordinary Simple Simon pipette for collection and handling of the samples
- An evaluation of the user-friendliness of MixxoCap
- An evaluation of the user-friendliness of Simple Simon PT

Materials and methods
The two primary health care centres were chosen in the light of the aim of this evaluation; testing the use of MixxoCap for capillary samples. Both centres had Simple Simon PT as their routine method for measurements of PT (INR). Arna Legekontor uses venous citrate whole blood samples for measurement of PT (INR). Legekontoret Kleppestø Senter uses capillary samples with use of the ordinary Simple Simon pipette. A total of 74 patients (84 measurements) were included in the evaluation. Capillary blood sampling with duplicate measurements on the Simple Simon PT systems was performed.

Results
When already familiar with capillary sampling technique for PT (INR), the precision obtained with capillary samples and MixxoCap under real-life conditions was good (CV 3,6%), and the recommended quality goal for precision was obtained. The same precision as achieved with venous samples using the ordinary Simple Simon pipette was obtained with capillary samples using MixxoCap on Simple Simon PT (CV approximately 3,6%). When not familiar with capillary sampling technique, the precision seems to get poorer when changing from venous samples to capillary samples and Mixxocap. Still the precision was good for results <2,5 INR. For results ≥2,5 INR, the precision was intermediate (CV 5,7%), but affected especially by one atypical duplicate. The two primary health care centres found the MixxoCap device easy to use, and they were satisfied with the device, as well as with the Simple Simon PT system.

Conclusion
Training and practise with the capillary sampling technique seem to be important for achieving good precision on PT (INR) results on Simple Simon PT. The new MixxoCap device seems to make the capillary blood sampling easier. When already familiar with capillary sampling technique, the precision obtained with capillary samples and MixxoCap under real-life conditions was good, with a CV <5%. When not familiar with capillary sampling technique, the precision was good for results <2,5 INR and intermediate for results ≥2,5 INR (CV 5,7%). The primary health care centres were satisfied with the MixxoCap device and the Simple Simon PT system.

Comments from the manufacturer
A letter with comments and additional information from the manufacturer is attached to the report.